



## ENZYMATIC THERAPY INCORPORATED

What **Better** feels like.™

March 14, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	Free radicals are naturally formed during cell metabolism and are also created by the body's immune system. The chain reaction can be controlled by antioxidants, which have the ability to share electrons while still maintaining molecular stability. Unfortunately, external factors, like pollution, cigarette smoke, and poor diet, can lead to significant free radical and ROS formation. If production of these unstable compounds becomes excessive and limited antioxidants are available in the body to neutralize them, cellular damage can occur.*	Vitamin C (Ascorbic Acid), Proprietary Flex Blend: hops (Humulus lupulus) (IsoOxygene™ brand) flower extract, ginger (Zingiber officinale) rhizome extract, Boswellia serrata gum extract, Bromelain, Japanese Sophora (Sophora japonica) Flower Bud, European Elder (Sambucus nigra) Berry Extract, Green Tea (Camellia sinensis) Leaf Extract, N-Acetylcysteine (NAC)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert C. Doster

Title: Senior Vice President of Scientific Affairs

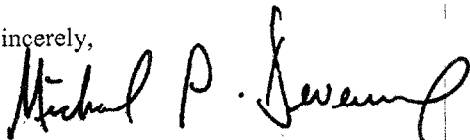
Date: 3/14/05

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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

A handwritten signature in black ink, reading "Michael P. Devereux". The signature is written in a cursive style with a large, stylized "M" and "D".

Michael P. Devereux  
Chief Financial Officer



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P: 503.582.8386 • F: 503.582.0467

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&  
**PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 • F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 • F: 920.469.4418 (Phyto)

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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	When compared to common vitamin antioxidants, the polyphenols in green tea were shown to exhibit significantly greater protection against free radical damage. Although its most common applications are immune support and energy enhancement, recent scientific research has focused on other beneficial effects of the herb. In particular, the ROS scavenger activity of green tea has been associated with reducing inflammation due to occasional overuse.*	Vitamin C (Ascorbic Acid), Proprietary Flex Blend: hops ( <i>Humulus lupulus</i> ) ( <i>IsoOxygene™</i> brand) flower extract, ginger ( <i>Zingiber officinale</i> ) rhizome extract, <i>Boswellia serrata</i> gum extract, Bromelain, Japanese Sophora ( <i>Sophora japonica</i> ) Flower Bud, European Elder ( <i>Sambucus nigra</i> ) Berry Extract, Green Tea ( <i>Camellia sinensis</i> ) Leaf Extract, N-Acetylcysteine (NAC)

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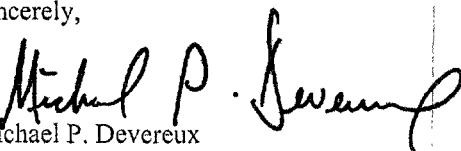
By: 

Robert C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 3/14/05

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Michael P. Devereux  
Chief Financial Officer



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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	Ginger is another phytochemical that has been used for centuries.* Recent studies have shown that ginger and its polyphenolic constituents, gingerol and shogaol, play a role in reducing inflammation due to occasional overuse.*	Vitamin C (Ascorbic Acid), Proprietary Flex Blend: hops ( <i>Humulus lupulus</i> ) ( <i>IsoOxygene™</i> brand) flower extract, ginger ( <i>Zingiber officinale</i> ) rhizome extract, Boswellia serrata gum extract, Bromelain, Japanese Sophora ( <i>Sophora japonica</i> ) Flower Bud, European Elder ( <i>Sambucus nigra</i> ) Berry Extract, Green Tea ( <i>Camellia sinensis</i> ) Leaf Extract, N-Acetylcysteine (NAC)

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

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### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas • PhytoPharmica  
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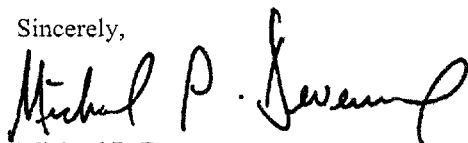
825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 • F: 888.570.6460 (Enzymatic)

P: 920.469.9099 • F: 920.469.4418 (Phyto)

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Michael P. Devereux  
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENT</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
FlexAgility™* Max	Bromelain supports optimum health by reducing prostaglandin and increasing blood flow.* A randomized, controlled, clinical trial found that bromelain reduces pain and stiffness due to occasional overuse.*	Bromelain

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Chief Financial Officer

FlexAgility Max 35e

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PRODUCT NAME	STATEMENT	INGREDIENT(S) TO WHICH THE CLAIM REFERS
FlexAgility™* Max	Shown to support collagen and connective tissue health.*	Green Tea (Camellia sinensis) Leaf Extract

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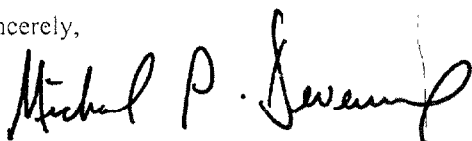
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FlexAgility™ Max	The ingredients in FlexAgility Max work together to provide triple action activity to reduce the pain and stiffness associated with occasional overuse or overexertion.* By providing three separate mechanisms of inflammatory mediation, the formula effectively supports optimum health.*	Proprietary Blend: Isooxygene, Ginger Root Extract, Boswellia Serrata, Rutin Flower Buds, Green Tea Leaf, Black Elderberry, Bromelain (2400 G.D.U. Pineapple Enzyme), Vitamin C (Ascorbic Acid), N-Acetylcysteine

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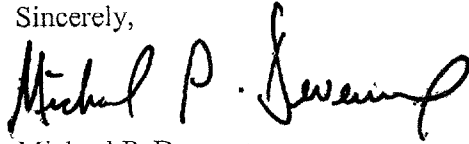
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Michael P. Devereux  
Chief Financial Officer



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FlexAgility™ Max	Ginger is also protective against peroxynitrite mediated oxidation.*	Ginger Root Extract

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FlexAgility Max 41e